

LAP7 Rec'd PCT/PTO 10 JAN 2006

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Attorney Docket #0288-034P/JAB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

U.S. Patent Application of S. Chava; S.R. Gorantla; and V.S.K. Indukuri

SN

10/553,821

Group Art Unit:

Unknown

Filed :

October 19, 2005

Examiner

Not Yet Assigned

For

Process For The Preparation Of Gabapentin Form-II

New York, NY January 5, 2006

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants wish to bring the attention of the Examiner to the references set forth on the annexed Form PTO/SB/08A which may be of interest in connection with examination of the identified application. One copy of each reference identified is submitted herewith.

U.S. Patents 4,024,175 and 4,087,544 disclose Gabapentin and processes for its preparation as hydrochloride and sodium salts.

U.S. 2003/0009055, U.S. 6,465,689, U.S. 5,091,567, WO 02/44123, WO 02/34709, WO 00/01660, WO 99/14184 and EP 1174418 disclose conversion of Gabapentin hydrochloride to a corresponding free amino acid by basic ion-exchange neutralization, followed by crystallization.

- 112 W-- 112 W- U.S. 4,894,476 discloses a method for converting the hydrochloride salt of Gabapentin into a crystalline monohydrate by eluting the aqueous solution through a basic ion-exchange resin to produce a slurry to which an alcohol is added.

U.S. 5,132,451, 5,095,148, 5,091,567 and 5,068,413 disclose hydrogenation of a cyano intermediate to liberate the free amino acid.

Respectfully submitted,

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JAB/cw ENCLS JAYA. BONDELL, ESQ., REG. #28.188

CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450.

on January 4, 2006

Carol L. Wood

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Under the Paperwork Reduction Act of 1995 Complete if Known Substitute for form 1449A/PTO JAN 1 0 2006 Application Number 10/553.821 INFORMATION DISCLOSURE Filing Date 10-19-05 STATEMENT BY APPLICANT First Named Inventor S. CHAVA Art Unit (Use as many sheets as necessary) Examiner Name Attorney Docket Number Sheet 1 of 0288-034P/IAB

U.S. PATENT DOCUMENTS					
Examiner Initials			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 4,024,175	05-17-1977	SATZINGER et al	
		US- 4,087,544	05-02-1978	SATZINGER et al	
		US- 4,894,476	01-16-1990	BUTLER et al	
		US- 5,068,413	11-26-1991	STEINER et al	
		US- 5,091,567	02-25-1992	GEIBEL et al	
		US- 5,095,148	03-10-1992	METTLER et al	
		US- 5,132,451	07-21-1992	JENNINGSet al	
		US- 6,465,689 B1	10-15-2002	BRYANS et al	
		US- 2003/0009055 A1	01-09-2003	VELARD1 et al	
		US-			

FOREIGN PATENT DOCUMENTS							
Examiner	Cite No.1	Foreign Patent Document		Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant	Т
		Country Code ³ Number ⁴	Kind Code ⁶ (if known)	MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	⊤ 6
		WO 99/14184	A1	03-25-1999	BRYANS et al		
		EP 1174418		01-14-2004	BOSCH LLADO et al		
		WO 00/01660	A1	01-03-2000	PAI OCCI et al		
		WO 02/34709	A1	05-02-2002	CANNATA et al		
		WO 02/44123	A1	06-06-2002	FERRARI et al		
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Examiner Signature	/Karl Puttlitz/	Date Considered	06/15/2008

"EXAMINE: Initial I reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation in roll conformance and nor considered. Include copy of this form with next communication to applicant! "applicahtr's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents a two users of the conformation of the patent document. The conformation of the year of the regin of the Emporor must precede the senial number of the patent document.

Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1,97 and 1,98. The information is required to obtain or retain a benefit by the public, which is to file (aproved by 35 U.S. -1.22 and 37 CFR 1, 1.4. This collection is estimated to lake 2 hours to complete, including aghtering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete its form and/or supplessions for reducing this burden, should be sent to the Chief amount of USPTO. The complete is complete its form and/or supplessions for reducing this burden, should be sent to the Chief amount of USPTO. The complete is complete to emplete the Stem and/or supplessions for reducing this burden, should be sent to the Chief amount of USPTO. The complete is the Chief and th